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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,953	11/03/2003	Jamie Crawford	5434-7	4325

27799 7590 07/11/2006

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EXAMINER	
MEHTA, BHISMA	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/699,953	CRAWFORD ET AL.
	Examiner	Art Unit
	Bhisma Mehta	3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *03 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 November 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/26/04, 6/14/04,* 6/17/04, 4/4/05, 8/29/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the slot and the lip being axially offset such that the hollow shield body is misaligned with a longitudinal axis of the cannula when the shield body is in the second position (the misalignment of the shield body with the longitudinal axis is not clearly seen) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 83 (line 5, page 11), 85 (line 7, page 14), and 88 (line 11, page 16). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 142, 167, and 194 (Figure 13). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are

not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "168" has been used to designate both a part of the actuator and a pin on the shield in Figure 14. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The disclosure is objected to because of the following informalities: There appears to be an error in line 1 of page 14 with the description of a "deployed second position shown in Fig. 6) as Figure 6 shows the medical device in a state prior to use. Also, reference character 65 has been used for a rim on line 4 of page 11 as shown in Figure 1 and a cam on line 16 of page 13 as shown in Figure 5.

Appropriate correction is required.

Claim Objections

6. Claims 9-13, 16, 17, 20, 23, 24, and 33-36 are objected to because of the following informalities: Claim 9 recites the limitations "said release mechanism" and "said retention means" in lines 1 and 3. Claims 12 and 13 recite the limitation "said catch" in line 2. Claim 16 recites the limitations "said shield" and "said fully inserted position" in line 5. Claim 17 recites the limitation "said shield" in line 5. Claim 20 recites the limitations "said shield" and "said retention means" in lines 1 and 2. Claim 23 recites the limitation "said shield" in line 2. Claim 24 recites the limitation "said shield" in line 4. Claim 34 recites the limitations "said retention device" and "said shield" in lines 3-5. There is insufficient antecedent basis for these limitations in these claims. Also, claim 33 is incomplete. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 13, 18, and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 13, it is unclear how the flexible arm can be connected to the front end of the syringe barrel as it has already been established in claim 8 that the retaining element comprises a flexible arm on the hollow shield body and thus the catch element has to be arranged on the syringe barrel as set forth in claim 7.

In claim 18, it is unclear what is meant by "preventing movement of said actuator away from said retracted position when said actuator is in said initial position" as the relationship between the retracted position and the initial potion with respect to the blocking device is not clearly established.

In claim 40, the use of "a second blocking device" is unclear because a first blocking device has not been established. Also, it is unclear what is meant by "preventing movement of said actuator away from said retracted position when said actuator is in said initial position" as the relationship between the retracted position and the initial position with respect to the blocking device is not clearly established.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Barrelle (U.S. Patent No. 6,776,777). Barrelle discloses a syringe assembly having a barrel (122), a needle cannula (128), a plunger (132), a hollow shield body (24), an urging member (28), and an actuator (22). The hollow shield is retractable to a position where the tip of the needle cannula is contained within the hollow shield body. The urging

member is a coil spring and is positioned between the hollow shield body and the barrel. In lines 20-41 of column 8, Barrelle teaches that the tubular barrel may be glass or plastic. In Figure 5, Barrelle show the barrel with a front portion arranged proximate the front end of the barrel. As to claims 6-8, 12, and 34, a retaining device is formed on the hollow shield body to releasably secure the shield body to the barrel where the retaining device causes a release of the shield body from the syringe barrel upon movement of the actuator. The retaining device comprises a flexible arm (56 or 58) on the shield body and a catch element (68) on the barrel. As to claims 9 and 10, as seen in Figure 19D and 19E, the cam (42) at the inner surface of the actuator releases the flexible arm (56 or 58) when the actuator is moved to the retracted position. As to claim 11, a locking surface is seen at the inner surface of the actuator where the shield body engages with the actuator in Figure 19E. As to claim 13, a flexible arm (68) is on the barrel and a catch (64) is on the shield body. As to the claims pertaining to a blocking device, a first blocking device on the barrel is capable of retaining the actuator in the retracted position and comprises an actuator catch (36) and a projection (134) as seen in Figures 19D and 19E. As to claim 16, the projection (88) on the flexible arm (68) of the barrel engages a shield catch (66) of the shield body when the shield is in a fully inserted position. As to claim 17, the projection (64) on the flexible arm (58) of the shield body engages a shield catch (68) of the barrel when the shield is in a first position as seen in Figure 19D. As to claims 18, 39, and 40, the second blocking device (242) for preventing movement of the actuator when the actuator is in the initial position is shown in Figure 21. As to claim 19, a portion (26) of the barrel is a removable clip

which is connectable to the barrel. As to claim 20, at least a portion of the shield and urging member are arranged in front of the medicament holding portion of the barrel. As to claims 22-25, the actuator also has a locking element or lip (48). As to claim 24, a pin (54) is received in a slot of locking element or lip (48) and the slot and the lip are axially offset. As to claim 35, the retaining device comprises a flexible arm (56 or 58) on the shield body and a catch element (68) arranged on a web (84) connected to the barrel. As to claim 36, a retaining element (84) is arranged on the flexible arm (68) of the barrel. As to claim 41, the means for urging the shield body is the spring (28) and the means for actuating the retaining means is the actuator (22). The means for releasably retaining the shield body to the barrel are the retaining device as discussed above.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Restelli et al (U.S. Patent No. 6,419,658), Shaw et al (U.S. Patent No. 6,494,863), and McWethy et al (U.S. Patent No. 7,004,929) disclose medical syringes where the needle is retracted within a hollow shield body.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BM

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER